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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,295

02/24/2004

Yoseph Shaaltiel

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07/22/2009

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

07/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,295	Applicant(s) SHAALTIEL, YOSEPH	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/26/08; 5/14/09; 5/20/09 and 5/27/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 99, 101-103, 105, 107, 108 and 110-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 99, 101-103, 105, 107, 108 and 110-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/26/2008; 5/20/2009; 5/27/2009.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/2009 has been entered.

Information Disclosure Statement

2. The information disclosure statements filed 11/26/2008; 5/20/2009; and 5/27/2009 have been considered and made of record.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 99, 101, 102, 105, 108, 110-114, and 116-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984).

With respect to claim 99, the reference of Arad et al. discloses a system (See Figures 1 and 2a) for culturing cells which includes a container (5,6) which comprises a harvester (10). Note the container (5,6) is considered sterilizable and disposable. With respect to the recited "a flow controller", the harvester (10) is positioned above the bottom of the container such that a portion of the culture medium would remain in the container when medium is removed using harvester (10).

While the reference of Arad et al. discloses the use of a bubbling device, claims 99 and 105 differ by reciting that each container includes a plurality of bubbling devices.

The reference of Hitzman discloses that it is conventional in the art of bioreactors to provide a plurality of bubbling devices (18) in each bioreactor vessel.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the bioreactor containers of the primary reference with a plurality of gas bubblers or spargers for the known and predictable result of bubbling the reactor vessel using an alternative means recognized in the art to achieve the same result, bubbling the culture medium with air and/or oxygen.

With respect to the bubble size required of claim 99, in the absence of further positively recited structure, the bubbler of the reference of Arad et al. is considered to be capable of

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providing bubbles of the claimed size since the size of the bubbles depends on factors such as the operation pressures and the properties of the culture medium.

With respect to the claimed “a culture of carrot cells”, while the combination of references above does not disclose a culture of carrot cells, the device as modified above is structurally the same as that instantly claimed and statements of intended use and/or the positive recitation of materials worked cannot patentably distinguish over the prior art rejection of record if the structure is capable of being used as intended and/or used with the material recited in the claim (See MPEP 2115).

With respect to claims 101 and 122-125, the device is capable of culturing the cells recited in these claims.

With respect to claim 102, the reference of Arad et al. disclose PVC as a possible material of construction (See column 3, lines 44-53).

With respect to claim 108, the container has a cylindrical geometrical configuration.

With respect to claim 110, in the absence of further positively recited structure, the bubbler of the reference of Arad et al. is considered to be capable of providing bubbles of the claimed size since the size of the bubbles depends on factors such as the operation pressures and the properties of the culture medium.

With respect to claim 111, the harvester (10) is positioned above the bottom of the container such that a portion of the culture medium would remain in the container when medium is removed using harvester (10).

With respect to claim 112, the bottom of the container includes upwardly sloping walls (See Figures 1 and 2a).

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With respect to claim 113, the reference discloses that the container can have a perimeter between 5 and 100 cm and a height between 100 and 250 cm (See column 3, line 65, to column 4, line 5).

With respect to claim 114, the device includes a support structure (4).

With respect to claim 116, the device includes a battery of containers (5,6)(See Figures 1 and 2a).

With respect to claim 117, the device includes a support structure (4).

With respect to claim 118, the device includes an additive inlet (10) connected to common inlet (9).

With respect to claim 119, the device includes a common harvesting piping (9).

With respect to claims 120 and 121, the device includes a common air inlet piping disposed within element (4) (See column 4, lines 51-55).

6. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984) taken further in view of Kalfon (EP 343 885).

The combination of the references of Arad et al. and Hitzman has been discussed above.

Claim 103 differs by reciting that the sidewalls of the container are made of a laminate of layers.

The reference of Kalfon discloses that it is conventional in the art of flexible bioreactors to manufacture the sidewalls of the container using a laminated material (See column 2, lines 32-46).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to manufacture the containers of the primary reference using laminated sheet material for the known and predicable result of using an alternative means of manufacture recognized in the art while providing a container of the required size and strength.

7. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984) taken further in view of Kobayashi (US 5,565,015).

The combination of the references of Arad et al. and Hitzman has been discussed above.

Claim 107 differs by reciting that the container has a box-like geometrical configuration.

The reference of Kobayashi discloses that it is conventional in the art to construct a bioreactor vessel using a box-like geometrical configuration (See Figure 3). The reference discloses that the container can be made of various shapes including tubular and a gusset type bag (See column 1, lines 53-61).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the container from any of the vessel shapes that are conventional in the art for the known and predicable result of providing a bioreactor vessel that can support the weight of its contents during use and can withstand sterilization conditions. The exact dimensions of the container would have been well within the purview of one having ordinary skill in the art while maintaining the require reaction conditions.

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8. Claim 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984) taken further in view of Whitney (GB 2 202 549).

The combination of the references of Arad et al. and Hitzman has been discussed above.

Claim 115 differs by reciting that the device includes a rigid cylindrical frame including a conical bottom.

The reference of Whitney discloses that it is conventional in the art to support a flexible bioreactor vessel using either a frame similar to the primary reference (See Figure 1) or using a cylindrical frame with a conical bottom (See Figure 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a cylindrical frame as disclosed by the reference of Whitney to support a reactor vessel for the known and predictable result of providing an alternative means recognized in the art to achieve the same result, support a flexible reactor vessel.

9. Claims 99, 101, 102, 105, 108, 110-114, and 116-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.).

With respect to claim 99, the reference of Arad et al. discloses a system (See Figures 1 and 2a) for culturing cells which includes a container (5,6) which comprises a harvester (10). Note the container (5,6) is considered sterilizable and disposable. With respect to the recited "a flow controller", the harvester (10) is positioned above the bottom of the container such that a portion of the culture medium would remain in the container when medium is removed using harvester (10).

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While the reference of Arad et al. discloses the use of a bubbling device, claims 99 and 105 differ by reciting that each container includes a plurality of bubbling devices.

The reference of Lee et al. discloses that it is conventional in the art of bioreactors to provide a plurality of bubbling devices (See “Photobioreactor Design and Construction, pages 1163-1164) in each bioreactor vessel.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the bioreactor containers of the primary reference with a plurality of gas bubblers or spargers for the known and predictable result of bubbling the reactor vessel using an alternative means recognized in the art to achieve the same result, bubbling the culture medium with air and/or oxygen.

With respect to the bubble size required of claim 99, the reference of Lee et al. discloses the use of 3 mm diameter nozzles for sparging the bioreactor (See “Photobioreactor Design and Construction, pages 1163-1164).

As a result, if the device of the modified primary reference is not inherently capable of providing the recited bubble sizes, it would have been obvious to one of ordinary skill in the art to employ a nozzle construction as suggested by the reference of Lee et al. in the system of the primary reference for the known and expected result of providing an art recognized means for sparging a bioreactor vessel.

With respect to the specific nozzle size and/or bubble size required of claims 99 and 110, it would have been obvious to one of ordinary skill in the art to determine the optimum nozzle size or bubble size based on the specifics of the cells to be cultured; the properties of the culture

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medium and/or size of the reactor while maintaining optimal reaction conditions within the reactor device.

With respect to the claimed “a culture of carrot cells”, while the combination of references above does not disclose a culture of carrot cells, the device as modified above is structurally the same as that instantly claimed and statements of intended use and/or the positive recitation of materials worked cannot patentably distinguish over the prior art rejection of record if the structure is capable of being used as intended and/or used with the material recited in the claim (See MPEP 2115).

With respect to claims 101 and 122-125, the device is capable of culturing the cells recited in these claims.

With respect to claim 102, the reference of Arad et al. disclose PVC as a possible material of construction (See column 3, lines 44-53).

With respect to claim 108, the container has a cylindrical geometrical configuration.

With respect to claim 110, in the absence of further positively recited structure, the bubbler of the reference of Arad et al. is considered to be capable of providing bubbles of the claimed size since the size of the bubbles depends on factors such as the operation pressures and the properties of the culture medium.

With respect to claim 111, the harvester (10) is positioned above the bottom of the container such that a portion of the culture medium would remain in the container when medium is removed using harvester (10).

With respect to claim 112, the bottom of the container includes upwardly sloping walls (See Figures 1 and 2a).

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With respect to claim 113, the reference discloses that the container can have a perimeter between 5 and 100 cm and a height between 100 and 250 cm (See column 3, line 65, to column 4, line 5).

With respect to claim 114, the device includes a support structure (4).

With respect to claim 116, the device includes a battery of containers (5,6)(See Figures 1 and 2a).

With respect to claim 117, the device includes a support structure (4).

With respect to claim 118, the device includes an additive inlet (10) connected to common inlet (9).

With respect to claim 119, the device includes a common harvesting piping (9).

With respect to claims 120 and 121, the device includes a common air inlet piping disposed within element (4) (See column 4, lines 51-55).

10. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.) taken further in view of Kalfon (EP 343 885).

The combination of the references of Arad et al. and Lee et al. has been discussed above.

Claim 103 differs by reciting that the sidewalls of the container are made of a laminate of layers.

The reference of Kalfon discloses that it is conventional in the art of flexible bioreactors to manufacture the sidewalls of the container using a laminated material (See column 2, lines 32-46).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to manufacture the containers of the primary reference using laminated sheet material for the known and predicable result of using an alternative means of manufacture recognized in the art while providing a container of the required size and strength.

11. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.) taken further in view of Kobayashi (US 5,565,015).

The combination of the references of Arad et al. and Lee et al. has been discussed above.

Claim 107 differs by reciting that the container has a box-like geometrical configuration.

The reference of Kobayashi discloses that it is conventional in the art to construct a bioreactor vessel using a box-like geometrical configuration (See Figure 3). The reference discloses that the container can be made of various shapes including tubular and a gusset type bag (See column 1, lines 53-61).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the container from any of the vessel shapes that are conventional in the art for the known and predicable result of providing a bioreactor vessel that can support the weight of its contents during use and can withstand sterilization conditions. The exact dimensions of the container would have been well within the purview of one having ordinary skill in the art while maintaining the require reaction conditions.

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12. Claim 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.) taken further in view of Whitney (GB 2 202 549).

The combination of the references of Arad et al. and Lee et al. has been discussed above.

Claim 115 differs by reciting that the device includes a rigid cylindrical frame including a conical bottom.

The reference of Whitney discloses that it is conventional in the art to support a flexible bioreactor vessel using either a frame similar to the primary reference (See Figure 1) or using a cylindrical frame with a conical bottom (See Figure 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a cylindrical frame as disclosed by the reference of Whitney to support a reactor vessel for the known and predictable result of providing an alternative means recognized in the art to achieve the same result, support a flexible reactor vessel.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 99, 101-103, 105, 107, 108 and 110-125 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,391,638. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 99, 101-103, 105, 107, 108 and 110-121 are generic to all that is recited in claims 1-45 of U.S. Patent No. 6,391,638. That is, claims 1-45 of U.S. Patent No. 6,391,638 fall entirely within the scope of claims 99, 101-103, 105, 107, 108 and 110-121 or, in other words, claims 99, 101-103, 105, 107, 108 and 110-121 are anticipated by claims 1-45 of U.S. Patent No. 6,391,638. With respect to the bubble size required of claim 99, in the absence of further positively recited structure, the bubbler of the patented claims is considered to be capable of providing bubbles of the claimed size since the size of the bubbles depends on factors such as the operation pressures and the properties of the culture medium.

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With respect to the claimed “a culture of carrot cells”, while the combination of references above does not disclose a culture of carrot cells, the device as modified above is structurally the same as that instantly claimed and statements of intended use and/or the positive recitation of materials worked cannot patentably distinguish over the prior art rejection of record if the structure is capable of being used as intended and/or used with the material recited in the claim (See MPEP 2115).

With respect to claims 101 and 122-125, the device is capable of culturing the cells recited in these claims.

14. Claims 99, 101-103, 105, 107, 108 and 110-125 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,391,638 in view of Lee et al.(Biotech. Bioeng.).

Claims 1-45 of the US patent encompass a device that is substantially the same as that instantly claimed.

With respect to the bubble size required of claim 99, the reference of Lee et al. discloses the use of 3 mm diameter nozzles for sparging the bioreactor (See “Photobioreactor Design and Construction, pages 1163-1164).

As a result, if the device of the modified primary reference is not inherently capable of providing the recited bubble sizes, it would have been obvious to one of ordinary skill in the art to employ a nozzle construction as suggested by the reference of Lee et al. in the system of the primary reference for the known and expected result of providing an art recognized means for sparging a bioreactor vessel.

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With respect to the specific nozzle size and/or bubble size required of claims 99 and 110, it would have been obvious to one of ordinary skill in the art to determine the optimum nozzle size or bubble size based on the specifics of the cells to be cultured; the properties of the culture medium and/or size of the reactor while maintaining optimal reaction conditions within the reactor device.

With respect to the claimed “a culture of carrot cells”, while the combination of references above does not disclose a culture of carrot cells, the device as modified above is structurally the same as that instantly claimed and statements of intended use and/or the positive recitation of materials worked cannot patentably distinguish over the prior art rejection of record if the structure is capable of being used as intended and/or used with the material recited in the claim (See MPEP 2115).

With respect to claims 101 and 122-125, the device is capable of culturing the cells recited in these claims.

Response to Arguments

15. With respect to the rejection of Claims 99-121 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,391,638, Applicant indicates that filing a terminal disclaimer will be considered upon indication of allowable subject matter by the Examiner.

In response, the obviousness-type double patenting rejection has been maintained since a terminal disclaimer has not been filed and the amended claims fail to patentably distinguish the instant claims over those of US Patent NO. 6,391,638.

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16. With respect to the rejection of Claims 99, 101, 102, 105, 108, 110-114, and 116-125 under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984) or over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.),

Applicant argues that the rejection is improper for the following reasons:

i) Applicant maintains that the container for growing microalgae, aerated with a gas (air) from a pipe introduced from above, and having a fluid inlet/outlet for filling and emptying as taught by Arad et al. is incompatible with the plant culture bioreactor of the system as claimed, and that none of the cited publications remedy the shortcomings of Arad et al. (See pages 6-8 of the response filed 5/14/2009)

In response, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. With respect to the claimed “a culture of carrot cells”, while the combination of references above does not disclose a culture of carrot cells, the device as modified above is structurally the same as that instantly claimed and statements of intended use and/or the positive recitation of materials worked cannot patentably distinguish over the prior art rejection of record if the structure is capable of being used as intended and/or used with the material recited in the claim (See MPEP 2115).

ii) Applicant wishes to point out that it is not at all understood that the container and culture conditions as taught by Arad et al. are suitable for culturing transformed carrot cells expressing a human lysosomal protein. Microalgae, such as the Dunaliella bardawilli grown in the container (see Arad et al., Example 2) are motile bi-flagellated cells approximately 10x6 µm in size enclosed by a thin

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later of elastic plasma membrane and are characterized by extreme halotolerance (capable of growth in 0.2 to 35% salinity) and rapid volume changes in response to variation in osmotic pressure. Carrot cells in suspension culture, in contrast, are non-motile, approximately 50-100 μm in size, and possess cellulose cell walls with high glucomannin content. Thus, factors governing shear forces, pH and osmotic effects suitable for use in the microalgae culture as taught by Arad et al. cannot be extrapolated to high volume suspension culture of recombinant carrot cells, as in the claimed invention. (See page 8-9 in the response filed 5/14/2009).

In response, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. With respect to the claimed “a culture of carrot cells”, while the combination of references above does not disclose a culture of carrot cells, the device as modified above is structurally the same as that instantly claimed and statements of intended use and/or the positive recitation of materials worked cannot patentably distinguish over the prior art rejection of record if the structure is capable of being used as intended and/or used with the material recited in the claim (See MPEP 2115). The culture conditions are immaterial in this case because the instant claims are device claims rather than method claims.

17. With respect to the rejection of Claim 103 under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984) taken further in view of Kalfon (EP 343 885); Claim 107 under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984) taken further in view of Kobayashi (US 5,565,015); Claim 115 under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US

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5,534,417) in view of Hitzman (US 4,519,984) taken further in view of Whitney (GB 2 202 549); Claim 103 under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.) taken further in view of Kalfon (EP 343 885); Claim 107 under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.) taken further in view of Kobayashi (US 5,565,015); and Claim under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Lee et al.(Biotech. Bioeng.) taken further in view of Whitney (GB 2 202 549); Applicant argues that the rejections are improper for the same reasons as set forth above with respect to the reference of Arad et al. and the additional references fail to make up for the deficiencies of the reference of Arad et al. (See page 9 of the response filed 5/14/2009).

In response, the Examiner maintains that the rejections are proper for the same reasons as set forth above with respect to the reference of Arad et al.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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**/William H. Beisner/
Primary Examiner
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WHB